

interval" of Figs. 6 - 8. (*See, e.g.*, Application at p. 13, lines 12-15; p. 15, lines 8-13 and lines 21-25). Accordingly, Applicant respectfully requests withdrawal of these rejections.

§102/103 Rejection of the Claims

1. Claims 1-91 were rejected under 35 U.S.C. § 102(f) on grounds that the applicant allegedly did not invent the claimed subject matter. The Office Action states that "[t]he application contains different inventors than the patent to Kramer et al. (6285907), but the application's claims are disclosed in Kramer et al." (Office Action at 3.) Applicant's review of the commonly-assigned Kramer et al. patent (the application for which was filed on the same day as the present patent application) did not identify any claims in the Kramer et al. patent that are identical to the presently pending patent claims. Applicant further notes that the Kramer et al. patent shares common inventors with the present patent application. Therefore, Applicant respectfully requests clarification or withdrawal of this rejection.

2. Claims 1-3, 26, 27, 58, 59, 63, 88, 89, and 91 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by or, in the alternative, under 35 U.S.C. 103(a) as allegedly obvious over Hill (U.S. Patent No. 5,814,085). The Examiner's burden of establishing a *prima facie* case of anticipation requires, among other things, the disclosure in a single prior art reference of each element of the claim under consideration. *See In re Dillon* 919 F.2d 688, 16 U.S.P.Q.2d 1897, 1908 (Fed. Cir. 1990) (*en banc*). However, Applicant is unable to find any teaching or suggestion in Hill of, among other things, recursively computing a first indicated pacing interval, for a most recent V-V interval (regardless of whether the most recent V-V interval is concluded by a paced or sensed beat) using not only a most recent V-V interval duration, but also a stored value of the first indicated pacing interval that was previously computed, as presently recited in claims 1, 58, 63, and 91 and, therefore, incorporated into their dependent claims.

Instead, Hill apparently requires, among other things, an average of three cycles that precede the cycle in which the most recent depolarization was sensed. (*See Hill* at 3:60-65.) This is not a recursive computation of a first indicated pacing interval. For an illustrative example, where the three cycles averaged by Hill are each concluded by a sensed beat, the computed average of such intrinsic beats would clearly be unaffected by any previously-

computed pacing interval. By contrast, each and every first indicated pacing interval computed according to the present claims uses a stored previously-computed value of the first indicated pacing interval.

The Office Action states that "although Hill uses an average in his computation, he still computes the new pacing interval based on the most recent interval length and is therefore recursive." (See Office Action at 4.) Applicant respectfully traverses this assertion. As illustrated by the above example, if the most recent observed interval is concluded by a sensed intrinsic heartbeat, rather than a pace delivered upon timeout of a computed escape interval, then Hill's newly computed pacing interval is completely independent of any previously-computed value of an indicated pacing interval—it is not recursive. Moreover, such operation according to Hill fails to meet the present express claim limitation requiring that the first indicated pacing interval be computed using, among other things, "a stored previously-computed value of the first indicated pacing interval."

One of the problems addressed by systems and methods of the present patent application is described in the background portion of the present specification—patients having atrial fibrillation (e.g., fast and irregular atrial heart rhythms) may suffer induced ventricular arrhythmias that severely compromise the pumping efficiency of the heart. (See Application at page 3, lines 7-10). "One aspect of the present system permits it to avoid rapid changes in heart rates." (Application at page 3, line 27). One of ordinary skill in the art would understand the claimed recursive computation of the first indicated pacing interval, which always uses a previously-computed value of the first indicated pacing interval—will be much less sensitive to sensed heart rate variations than the averager of Hill, which can severely skew toward a higher heart rate after even three consecutive sensed short intervals. It is believed that such excessive pacing rates could result in ischemia and even a myocardial infarction. By contrast, a recursive computation that uses the previously-computed indicated pacing interval (regardless of whether the most recent pacing interval is paced or sensed) will be much less sensitive to sensed short intervals. Therefore, the recursive implementation of the present patent application is believed to be much better suited for patients with atrial fibrillation.

Hill expressly teaches away from rate stabilization that reduces sensitivity to sensed short

intervals. In the "Summary of the Invention," Hill contrasts his rate stabilization technique with other rate stabilization pacemakers:

While these pacemakers accomplish the desired result of preventing the short-long cycle patterns sometimes associated with the onset of tachycardias, they do not take into account the underlying heart rate or the degree of prematurity of the sensed heart depolarization in calculating the value of the increment. The present invention varies the increment following a cycle ending in a sensed depolarization as a function of the underlying heart rate and may additionally vary the increment as a function of the prematurity of the most recently sensed depolarization relative to the preceding depolarization. . . . The mechanism of the present invention for determining the duration of the increment provides for a more rapid return to a lower underlying heart rate, while still avoiding the short-long interval pattern sometimes associated with the onset of tachycardia. It is believed that this mechanism of controlling the escape intervals in a rate stabilization pacing mode may assist in avoiding arrhythmias by reducing the amount of pacemaker-induced fluctuation of the heart's refractory period.

(Hill at column 1, line 55 to column 2 line 13.) Hill teaches rate stabilization that attempts to more closely follow sensed heart rate up and down so that the pacing rate doesn't get stuck up at high heart rates. By contrast, the recursive implementation of the present patent application decreases sensitivity to sensed short intervals so that the indicated pacing rate is not driven up to excessively high heart rates in the first place.

Because Hill does not teach or suggest a recursively-computed first indicated pacing interval that uses, among other things, "a stored previously-computed value of the first indicated pacing interval," and in fact expressly teaches away from such an implementation's reduced sensitivity to short sensed intervals that typically accompany , Applicant respectfully submits that claims 1-3, 26, 27, 58, 59, 63, 88, 89, and 91 are neither anticipated by, nor obvious in view of Hill. Accordingly, Applicant respectfully requests withdrawal of these rejections and allowance of these claims.

3. Claims 23-25, 64, and 67-70 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Hill (U.S. Patent No. 5,814,085). Because these dependent claims incorporate limitations requiring recursive computation of the first indicated pacing interval using, among other things, the previously-computed stored value of the first indicated pacing interval, Applicant respectfully submits that Hill does not teach or suggest all limitations of these claims

for the reasons discussed above.

Moreover, the Office Action asserts:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable pacing device as taught by Hill with the sensor, register, and basing the pacing therapy on a second pacing interval based on the sensor, basing the pacing therapy on the shorter of the two intervals, and providing a bounded range for the intervals since it was known in the art that pacemakers include sensors, registers, and base the pacing therapy on a second pacing interval based on the sensors, base the pacing therapy on the shorter of the two intervals, and provide a bounded range for the intervals to provide the pacer with other indicators of physiological demand so the pacer can control the pacing rate with a combination of the other indicators and limit the pacing rate to selected rates.

(Office Action at 5.) To the extent that this statement is based on the Examiner's personal knowledge of using a sensor in combination with a recursively-computed pacing interval that uses, among other things, the previously-computed stored value of the first indicated pacing interval, Applicant objects to the Examiner's reliance on Official Notice and respectfully requests a reference supporting such a teaching or suggestion. *See* M.P.E.P. § 2144.03. Applicant respectfully submits that any such suggestion is based on impermissible hindsight obtained from page 17 of the Applicant's own disclosure. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2143; *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). Absent such an objective teaching or suggestion in the prior art, Applicant respectfully submits that no *prima facie* case of obviousness exists with respect to these claims.

Moreover, even if one assumes that sensors, registers, etc. are known in the art, the Examiner has not provided any evidence of any motivation to combine such a sensor with a recursively-computed pacing interval that uses, among other things, the previously-computed stored value of the first indicated pacing interval. The Federal Circuit has recently reaffirmed the Examiner's burden of conducting and articulating a specific, thorough, and searching inquiry based on objective evidence of record as to whether there exists a "motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant." *In re Lee*, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002), citing *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). In view of the above, Applicant respectfully submits that claims 23-25, 64, and 67-70 are

RESPONSE UNDER 37 C.F.R. § 1.11

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not obvious over Hill, and respectfully requests withdrawal of this rejection and allowance of these claims.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612 373-6951) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 28 day of May, 2002.

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